REMARKS

Claims 15, 58, and 62 have been amended, claims 1-8, 10-12, 17-45, and 48-56 are cancelled, and claims 9, 13-16, 46, 47, 57-62 are pending in the instant application. Support for the amendments to the claims can be found in the specification at, for example, page 23, lines 2-12; and in Figures 1, 2, and 3. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Declaration

The Office Action states that because the declaration improperly lists U.S. Application No. 09/599,087 as a "Prior Foreign Application," and therefore, improperly claims the benefit of the earlier filing date of U.S. Application No. 09/599,087, a new declaration in compliance with 37 C.F.R. 1.67(a) is required.

Applicants submit a replacement copy of the executed Supplemental Declaration filed January 16, 2002 in response to the Office Action mailed July 16, 2001. Applicants contend that, pursuant to 37 C.F.R. § 1.67(a), the Supplemental Declaration properly claims the benefit of priority under 35 U.S.C. § 120 from U.S. Application Serial No. 09/599,087, filed June 21, 2000, and acknowledges Applicants' duty to disclose all information known by Applicants to be material to patentability which became available between the filing date of the prior application and the national filing date of the present application.

2. Election/Restriction

The Office Action states that newly amended claims 15, 46, 47, 58-60, and 62 are directed, in part, to inventions that are independent or distinct from the invention originally claimed because claims 15, 58, and 62 encompass the non-elected invention of Group 3, as identified in the Restriction Requirement mailed April 27, 2001, as well as a multitude of other distinct inventions comprising amino acid sequences that differ from the amino acid sequence of the elected invention. The Action also states that claims 15, 46, 47, 58-60, and 62, to the extent that the claims are drawn to non-elected inventions, are withdrawn from consideration as being directed to a non-elected invention.

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Applicants have amended claims 15, 58, and 62 to recite that the claimed polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 5, wherein the isoleucine residue at position 12 may be substituted with a methionine residue, the serine residue at position 18 may be substituted with a cysteine residue, the isoleucine residue at position 19 may be substituted with a valine residue, the threonine residue at position 22 may be substituted with a serine residue, the lysine residue at any of positions 25, 61, or 64 may be substituted with an arginine residue, the arginine residue at position 26, may be substituted with a lysine residue, the arginine residue at position 27 may be substituted with a histidine residue, the asparagine residue at position 51 may be susbtituted with a threonine residue, the histidine residue at position 55 may be substituted with an asparagine residue, the valine residue at position 81 may be substituted with an isoleucine residue; and the residues at any of positions 5, 8, 10, 11, 14, 17, 20, 31, 32, 33, 34, 36, 37, 38, 39, 40, 43, 44, 46, 47, 48, 49, 50, 52, 57, 59, 62, 65, 66, 67, 68, 69, 70, or 71 may be substituted with any naturally occurring amino acid. Exhibit A indicates that the amino acid sequences of SEQ ID NO: 5 and SEQ ID NO: 2 differ, *inter alia*, in that the threonine, arginine, and leucine residues at positions 37-39 of the amino acid sequence of SEQ ID NO: 5 are deleted in the amino acid sequence of SEQ ID NO: 2. As a result, the amino acid sequence of SEQ ID NO: 2 is three amino acids shorter than the amino acid sequence of SEQ ID NO: 5. Exhibit A also indicates that the amino acid sequences of SEQ ID NO: 5 and SEQ ID NO: 7 differ, *inter alia*, in that the threonine, arginine, and leucine residues at positions 37-39 and the leucine residue at position 65 of SEQ ID NO: 5 are deleted in the amino acid sequence of SEQ ID NO: 7. As a result, the amino acid sequence of SEQ ID NO: 7 is four amino acids shorter than the amino acid sequence of SEQ ID NO: 5. Applicants contend that neither the amino acid sequence of SEQ ID NO: 2 nor the amino acid sequence of SEQ ID NO: 7 can be constructed from the amino acid sequence of SEQ ID NO: 5 simply by making amino acid substitutions in the amino acid sequence of SEQ ID NO: 5. Applicants contend that because the genus of polypeptides recited in amended claims 15, 58, and 62 encompasses only substituted variants of the amino acid sequence of SEQ ID NO: 5, amended claims 15, 58, and 62 do not encompass the non-elected invention of Group 3, and claims 15, 46, 47, 58-60, and 62 are not directed to inventions that are independent or distinct from the invention originally claimed.

In addition, Applicants note that claim 14, as originally filed, recited an isolated polypeptide comprising the amino acid sequence selected from the group consisting of the amino acid sequence

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

as set forth in either SEQ ID NO: 3 or SEQ ID NO: 6, optionally further comprising an amino-terminal methionine; an amino acid sequence for an ortholog of either SEQ ID NO: 2 or SEQ ID NO: 5; an amino acid sequence which is at least about 70 percent identical to the amino acid sequence of either SEQ ID NO: 2 or SEQ ID NO: 5, wherein the polypeptide has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5; a fragment of the amino acid sequence set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 comprising at least about 25 amino acid residues, wherein the fragment has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5, or is antigenic; and an amino acid sequence for an allelic variant or splice variant of the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5, the amino acid sequence encoded by the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755, or any of the polypeptide sequences recited above. Applicants also note that claim 15, as originally filed, recited an isolated polypeptide comprising the amino acid sequence selected from the group consisting of the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 with at least one conservative amino acid substitution; the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 with at least one amino acid insertion; the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 with at least one amino acid deletion; the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 which has a C- and/or N- terminal truncation; and the amino acid sequence as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5 with at least one modification selected from the group consisting of amino acid substitutions, amino acid insertions, amino acid deletions, C-terminal truncation, and N-terminal truncation; wherein any of the polypeptides recited above has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5. Applicants further note that because claims 14 and 15 were *only* assigned to groups 3 and 4 in the Restriction Requirement mailed April 27, 2001, the claims of group 3 must be directed to murine Secs-1 polypeptides and murine Secs-1 polypeptide variants, and the claims of group 4 must be directed to human Secs-1 polypeptides and human Secs-1 polypeptide variants. Applicants contend that because the genus of human Secs-1 polypeptide variants recited in originally filed claims 14 and 15, and assigned to the invention of group 4, encompasses each and every member of the genus of human Secs-1 polypeptide variants recited in amended claims 15, 58, and 62, amended claims 15, 58, and 62 do not encompass the non-elected invention of Group 3, and claims 15, 46, 47,

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

58-60, and 62 are not directed to a multitude of other distinct inventions comprising amino acid sequences that differ from the amino acid sequence of the elected invention.

Applicants, therefore, respectfully request that the full scope of the subject matter recited in claims 15, 46, 47, 58-60, and 62 be considered.

3. Grounds of Objection and Rejection Withdrawn

The Office Action states that the grounds of rejection of claims 9, 13, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, second paragraph, set forth in the Office Action mailed April 23, 2002 have been withdrawn because even though the nucleotide sequence of a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755 is not actually described in the specification, the DNA insert is defined at page 2, lines 27-30 of the specification to be a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. The Action also states that it is therefore clear that while the nucleotide sequence of the DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755 differs from SEQ ID NO: 4, it nevertheless encodes the human Secs-1 polypeptide (*i.e.*, the polypeptide of SEQ ID NO: 5). The Action further states that the DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755 is thus regarded as the portion of the cloned nucleic acid molecule in the deposit which encodes the human Secs-1 polypeptide and which does not comprise a portion of the parental cloning vector.

Applicants first wish to thank the Examiner for attempting to clarify the record. Applicants respectfully contend, however, that the portion of the specification cited by the Examiner, which contains language that is nearly identical to and which provides explicit support for originally filed claim 2, does not define the DNA insert in ATCC Deposit No. PTA-1755 as comprising a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. Applicants contend, instead, that the specification at page 2, line 21 to page 3, line 11 defines a genus of nucleic acid molecules that includes a nucleotide sequence encoding a polypeptide which is at least about 70 percent identical to the polypeptide as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5, wherein the encoded polypeptide has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5; a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence as set forth in either SEQ ID NO: 1 or SEQ ID NO: 4, the nucleotide sequence

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

of the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755, or the nucleotide sequence recited at page 2, lines 23-26; a region of the nucleotide sequence of either SEQ ID NO: 1 or SEQ ID NO: 4, the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755, the nucleotide sequence recited at page 2, lines 23-26, or the nucleotide sequence recited at page 2, lines 27-30, encoding a polypeptide fragment of at least about 25 amino acid residues, wherein the polypeptide fragment has an activity of the encoded polypeptide as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5, or is antigenic; a region of the nucleotide sequence of either SEQ ID NO: 1 or SEQ ID NO: 4, the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755, or any of the nucleotide sequences recited at page 2, lines 23-26, page 2, lines 27-30, or page 3, lines 1-5, comprising a fragment of at least about 16 nucleotides; a nucleotide sequence which hybridizes under moderately or highly stringent conditions to the complement of any of the nucleotide sequences recited above; and a nucleotide sequence complementary to any of the nucleotide sequences recited above. Applicants contend, therefore, that it is clear that the portion of the specification cited by the Examiner (*i.e.*, page 2, lines 27-30) merely recites a genus of nucleic acid molecules comprising nucleotide sequences that encode an allelic variant or splice variant of (a) the nucleotide sequence as set forth in either SEQ ID NO: 1 or SEQ ID NO: 4, (b) the nucleotide sequence of the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755, or (c) a nucleotide sequence encoding a polypeptide which is at least about 70 percent identical to the polypeptide as set forth in either SEQ ID NO: 2 or SEQ ID NO: 5, wherein the encoded polypeptide has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5.

Moreover, Applicants respectfully disagree with the Action's assertion that the nucleotide sequence of the DNA in ATCC Deposit No. PTA-1755 encodes the polypeptide of SEQ ID NO: 5. As described in Applicants' response to the Advisory Action mailed September 23, 2002, Applicants amended claim 13 to recite an isolated polypeptide comprising an amino acid sequence as set forth in SEQ ID NO: 5, *or* an amino acid sequence encoded by a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755. Applicants similarly amended claims 9 and 16. Applicants contend that if the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755 were construed as simply encoding the polypeptide of SEQ ID NO: 5, the language of claims 9(a)(iii), 13(a), and 16(c) would be rendered superfluous as redundant. Applicants, therefore, respectfully

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

contend that the DNA insert in ATCC Deposit No. PTA-1755 is more properly defined as comprising a nucleotide sequence that encodes *a* Secs-1 polypeptide.

3. Objection to the Specification

The Office Action asserts an objection to the specification because of the use of improperly demarcated trademarks.

Applicants have amended the specification as indicated above to identify the trademarks appearing in the instant application by capitalizing each letter of the mark or by using a proper trademark symbol (*i.e.*, ®). Applicants, therefore, respectfully request that this objection be withdrawn.

4. Objection to claims 15, 46, 47, 58-60, and 62

The Office Action asserts an objection to claims 15, 46, 47, 58-60, and 62 as being drawn in the alternative to the subject matter of non-elected inventions.

As described in section 2 above, Applicants have amended claims 15, 58, and 62 so that they are no longer drawn in the alternative to the subject matter of non-elected inventions. Applicants, therefore, respectfully request that this objection be withdrawn.

5. Rejections of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 14, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action states that the disclosures and figures referred to in Applicants' response to the Advisory Action mailed September 23, 2002 as providing support for the limitation "but not more than 80 amino acid residues" do not appear to provide a sufficient antecedent basis for recitation of this limitation in the claims, and therefore, that the recitation of this limitation appears to introduce new matter.

Applicants note that claim 14 recites, in part, an isolated polypeptide comprising a fragment of the amino acid sequence set forth in SEQ ID NO: 5 comprising at least about 25 amino acid

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

residues, but not more than 80 amino acid residues. Applicants also note that amended claim 57 recites, in part, a polypeptide produced by a process comprising culturing a host cell containing a vector comprising a nucleic acid molecule having a nucleotide sequence of a region of the recited nucleotide sequences, wherein the polypeptide produced is a fragment of the amino acid sequence set forth in SEQ ID NO: 5 of at least about 25 amino acid residues, but not more than 80 amino acid residues. Applicants also note that the amino acid sequence of the human Secs-1 polypeptide described in Figure 2 and in SEQ ID NO: 5 is 81 amino acids in length. Applicants further note that the specification defines the term "Secs-1 polypeptide fragment" as referring to a polypeptide that comprises an amino-terminal and/or carboxyl-terminal truncation of the polypeptide of SEQ ID NO: 5 (page 11, lines 12-15). Applicants contend that because claims containing the limitation "but not more than 80 amino acid residues" recite only *fragments* of the polypeptide of SEQ ID NO: 5, and the human Secs-1 polypeptide of SEQ ID NO: 5 comprises 81 amino acids, then perforce a fragment of the polypeptide must necessarily be a truncated form of the human Secs-1 polypeptide of SEQ ID NO: 5 as defined in the specification. Applicants respectfully contend that their disclosure provides explicit support for this limitation in, for example, Figure 2 and SEQ ID NO: 5, and at page 11, lines 12-15. Withdrawal of this rejection is therefore respectfully solicited.

The Office Action also asserts a rejection of claims 9, 13, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention. The Action states that because the DNA insert in ATCC Deposit No. PTA-1755 is not set forth in the specification, it is apparent that this deposit would be required to make and use the invention. The Action also states that because this deposit does not appear to be known or publicly available, or capable of being reproducibly isolated by a repeatable method set forth in the specification, and the claims require the use of this deposit, the mere reference to the deposit in the specification is insufficient to ensure that all of the conditions of 37 C.F.R. §§ 1.803-1.809 have been met. The Action further states that a deposit made in full compliance with 37 C.F.R. §§ 1.803-1.809 would satisfy the requirements of 35 U.S.C. § 112, first paragraph, provided that Applicants submit a statement by an attorney of record over his or her signature and registration number, stating that a deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of

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300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

the deposited material will be irrevocably removed upon the granting of a patent.

Pursuant to the Examiner's request, Applicants' representative submits the following statement: Applicants deposited cDNA encoding human Secs-1 polypeptide with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, VA 20110-2209. The deposit was accepted by the ATCC, an International Depository Authority, under the provisions of the Budapest Treaty, and the deposit was designated as PTA-1755. A copy of the ATCC receipt for this deposit, showing the patent deposit designation (Accession No. PTA-1755) and the date on which the deposit was received by the ATCC (April 25, 2000) is attached. Pursuant to 37 C.F.R. § 1.808(a)(2), the deposit was made under conditions that assure that all restrictions imposed by the depositors on the availability to the public of the deposited material would be irrevocably removed upon the granting of a patent relying on the deposited biological material. In making the deposit, Applicants acknowledged their responsibility, pursuant to 37 C.F.R. § 1.805, to provide a replacement or supplemental deposit if the depository possessing the deposit is unable to furnish samples thereof or is able to furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification. Applicants contend that all the requirements of 37 C.F.R. §§ 1.801-1.809 have been met. *In re Lundak,* 225 U.S.P.Q. 90 (Fed. Cir. 1985). Withdrawal of this rejection is therefore respectfully solicited.

Applicants respectfully contend that rejections based on 35 U.S.C. § 112, first paragraph, have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

CONCLUSIONS

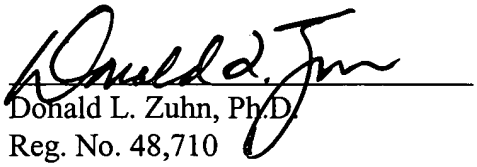
Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

Dated: August 20, 2003

By: 
Donald L. Zuhn, Ph.D.
Reg. No. 48,710

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001